United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL AND LISA WENDELL, for themselves and as successors in interest to MAXX WENDELL, deceased,

Plaintiffs,

v.

JOHNSON & JOHNSON, et al.,

Defendants.
_____/

No. C 09-04124 CW

ORDER DENYING ABBOTT LABORATORIES' MOTION TO DISMISS AND GRANTING REMAINING DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS, WITH LEAVE TO AMEND

This is a products liability action concerning three prescription drugs, Remicade, Humira and 6-mercaptopurine. Defendant Abbott Laboratories (Abbott Labs), the manufacturer of Humira, moves to dismiss all claims alleged against it. The remaining non-Abbott Defendants move for judgment on the pleadings. Plaintiffs oppose the motions. Having considered all of the parties' papers, the Court denies Abbott Labs' motion to dismiss and grants non-Abbott Defendants' motion for judgment on the pleadings, with leave to amend.

BACKGROUND

The following facts are alleged in the first amended complaint. Plaintiffs allege that Defendants' products, used either alone or in combination, resulted in Maxx Wendell's hepatosplenic T-Cell lymphoma in 2007. Plaintiffs' claims against Abbott Labs concern the company's failure to warn adequately of lymphoma risks associated with the use of Humira for a purpose not

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approved by the U.S. Food and Drug Administration (FDA).

In 1998, at the age of twelve, Maxx Wendell was diagnosed with inflammatory bowel disease and ulcerative colitis. Initially he was treated with a course of 6-mercaptopurine and prednisone, a steroid. First Amended Complaint (1AC) ¶ 52. 6-mercaptopurine[1] is a "purine analog which interfered with nucleic acid biosynthesis and has been found to be active against human leukemias." Id. ¶ 48. The only FDA-approved use of 6-mercaptopurine is for the "remission induction and maintenance therapy of acute lymphatic leukemia." Id.

In May, 2002, Maxx's physicians recommended adding Remicade to his treatment regimen[2] while weaning him from steroids. In June or July, 2002, Maxx received his first dose of Remicade. Remicade is a Tumor Necrosis Factor (TNF)-∝ inhibitor, which is designed to suppress the immune system in ways that can reduce the symptoms of autoimmune disorders, such as Crohn's disease and rheumatoid arthritis. Id. ¶ 36. In November, 2006, Maxx's doctors replaced his intake of Remicade with Humira. Humira is also a TNF-∝ inhibitor with anti-inflammatory effects that provides relief for many symptoms affecting rheumatoid arthritis. Id. ¶ 42. Humira is designed and manufactured by Abbott Labs. Id. at ¶ 18. He received at least five doses of Humira between November, 2006 and June, 2007. Id. at ¶ 56.

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[1]6-mercaptopurine manufactured by Defendant Smithkline Beecham is marketed under the name Purinethol. Teva Pharmaceuticals USA, Gate Pharmaceuticals and Par Pharmaceuticals manufacture generic 6-mercaptopurine. 1AC. ¶¶ 19-22.

[2]Remicade is manufactured by Defendants Johnson & Johnson and Centocor, Inc. Compl. ¶ 16.

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In July, 2007, doctors diagnosed Maxx with hepatosplenic T-cell lymphoma. Id. at ¶ 57. Despite aggressive chemotherapy and other treatments, Maxx died on December 19, 2007.

Plaintiffs allege that, following FDA approval of "Remicade in 1998 for treatment of rheumatoid arthritis and Crohn's disease in adults, it became common practice to prescribe 6-mercaptopurine in combination concomitantly with TNF-blockers like Remicade or Humira in the treatment of autoimmune disorders." Id. at ¶ 50. Plaintiffs allege that such use, "which was not approved by the FDA -- was not only known to Defendants herein but encouraged and/or promoted and/or fostered and/or otherwise enabled by Defendants herein and each of them without adequate testing on the safety and/or efficacy of such combination use or in the pediatric or young adult populations." Id.

In their original complaint Plaintiffs asserted ten causes of action against all Defendants: (1) fraud and deceit, (2) negligence, recklessness and gross negligence, (3) negligent misrepresentation, (4) negligence, (5) negligence per se, (6) strict liability, (7) breach of express warranty, (8) breach of implied warranty, (9) violation of Business and Professions Code Section 17200, et seq. and (10) wrongful death. Abbott Labs moved to dismiss this complaint and the remaining Defendants answered. On January 20, 2010, the Court granted Abbott Labs' motion in part and on February 9, 2010, Plaintiffs filed an amended complaint. The amended complaint is virtually identical to the original complaint, except that it alleges the first ten causes of action listed above "Against All Defendants Except Abbott Laboratories" and it alleges two separate causes of action against Abbott Labs

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for negligence and strict liability. Abbott Labs has moved to dismiss this complaint and the remaining non-Abbott Defendants have moved for judgment on the pleadings.

LEGAL STANDARD

I. Motion to Dismiss For Failing to State a Claim

A complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). When considering a motion to dismiss under Rule 12(b)(6) for failure to state a claim, dismissal is appropriate only when the complaint does not give the defendant fair notice of a legally cognizable claim and the grounds on which it rests. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). In considering whether the complaint is sufficient to state a claim, the court will take all material allegations as true and construe them in the light most favorable to the plaintiff. NL Indus., Inc. v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). However, this principle is inapplicable to legal conclusions; "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not taken as true. Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949-50 (2009) (citing Twombly, 550 U.S. at 555).

II. Motion for Judgment on the Pleadings

Rule 12(c) provides, "After the pleadings are closed -- but early enough not to delay trial -- a party may move for judgment on the pleadings." "Judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material issue of fact remains to be resolved and that it is entitled to judgment as a matter of law. However, judgment on the pleadings is improper when the district court goes beyond the

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pleadings to resolve an issue; such a proceeding must properly be treated as a motion for summary judgment." Hal Roach Studios, Inc. v. Richard Feiner and Co., Inc., 896 F.2d 1542, 1550 (9th Cir. 1990).

DISCUSSION

I. Motion for Judgment on the Pleadings

A. Timing of the Motion

Plaintiffs argue that non-Abbott Defendants cannot file a motion for judgment on the pleadings until all Defendants have answered. Plaintiffs assert that, because Abbott Labs has a motion to dismiss pending, it would be premature for the Court to consider the motion for judgment on the pleadings. Plaintiffs are not correct.

As noted above, a party may move for judgment on the pleadings after the "pleadings are closed." Fed. R. Civ. P. 12(c). The instant motion for judgment on the pleadings concerns the first ten causes of action, which were filed against non-Abbott Defendants only. Those Defendants have answered those causes of action; thus, those pleadings are "closed." Nothing in the Federal Rules of Civil Procedure or the policies behind those rules prevents the Court from deciding non-Abbott Defendants' motion for judgment on the pleadings at this juncture. Accordingly, the motion is ripe for decision.

B. Analysis

Non-Abbott Defendants move for judgment on the pleadings as to all claims plead against them. Plaintiffs respond by arguing that their causes of action for negligence and strict liability state

proper claims for relief.[3] Plaintiffs' opposition papers do not address the remaining causes of action; and, at the hearing on the motion, Plaintiffs agreed to dismissal of those claims.

In its January 20, 2010 Order, the Court dismissed all of the claims against Abbott Labs in the original complaint. In particular, it dismissed the negligence and strict liability claims because Plaintiffs' allegations failed to specify any tortious conduct by Abbott Labs.

> Plaintiffs simply recite the elements of each cause of action and repeat the same failure-to-warn allegations. Plaintiffs fail to allege how Abbott Labs' warnings about Humira were inadequate, how it was negligent in failing to satisfy any other duty of care alleged or how it violated any specific California consumer protection law that would serve as the basis of Plaintiffs' negligence per se claim. Plaintiffs' "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are insufficient to state a claim. Iqbal, 129 S. Ct. at 1949-1950.

Order at 9. Each of the claims in the original complaint asserted identical allegations "Against All Defendants." No individualized allegations were asserted against any Defendant. In the amended complaint, Plaintiffs have not changed the allegations against the non-Abbott Defendants. Thus, just as the original complaint failed to put Abbott Labs on notice of the claims asserted against it, the amended complaint similarly fails to notify the non-Abbott Defendants. Therefore, the Court grants non-Abbott Defendants' motion for judgment on the pleadings, and grants Plaintiffs leave to amend.

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[3]These claims comprise Plaintiffs' second, fourth and sixth causes of action.

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II. Motion to Dismiss

A. Warning Label

Abbott Labs first argues that Plaintiffs' negligence and strict liability claims should be dismissed because the Humira warnings regarding lymphoma were adequate. As noted above, Maxx took Humira between November, 2006 and June, 2007. Before the FDA approved the use of Humira to treat Crohn's disease in February, 2007, it was approved for the treatment rheumatoid arthritis. The drug contained the following warnings pertaining to the increased risk of lymphoma:

> In the controlled portions of clinical trials of all the TNF-blocking agents, more cases of lymphoma have been observed among patients receiving TNF blockers compared to control patients. In controlled trials in patients with rheumatoid arthritis, 2 lymphomas were observed among 1922 HUMIRA-treated patients versus 1 among 947 control patients. In combining the controlled and uncontrolled open-label portions of these clinical trials with a median duration of approximately 3 years, including 3042 patients and over 8,500 patient-years of therapy, the observed rate of lymphomas is approximately 0.15 /100 patient-years. This is approximately 4-fold higher than expected in the general population. Rates in clinical trials for HUMIRA cannot be compared to rates of clinical trials of other TNF blockers and may not predict the rates observed in a broader patient population. Patients with rheumatoid arthritis, particularly those with highly active disease, are at a higher risk for the development of lymphoma.

Humira Label at 13-14, August 28, 2006.[4] Under the heading, "Other Adverse Events," the label generally stated:

> Neoplasia: Adenoma, carcinomas such as breast, gastrointestinal, skin, urogenital, and others; lymphoma and melanoma.

Id. at 21. The warning also noted:

> There have been very rare cases of certain kinds of cancer

[4] The Court takes judicial notice of the FDA drug labels at issue in this case. See In re Amgen Sec. Litig., 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008)

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> in patients taking HUMIRA or other TNF blockers. People with more serious RA that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you take HUMIRA or other TNF blockers, your risk may increase.

Id. at 27.

After the FDA approved Humira for Crohn's disease in February, 2007, the label described the lymphoma risk as follows:

> In the controlled portions of clinical trials of all the TNF-blocking agents, more cases of lymphoma have been observed among patients receiving TNF blockers compared to control patients. In controlled trials in patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease, 2 lymphomas were observed among 2887 HUMIRA-treated patients versus 1 among 1570 control patients. In combining the controlled and uncontrolled open-label portions of these clinical trials with a median duration of approximately 2 years, including 4843 patients and over 13,000 patient-years of therapy, the observed rate of lymphomas is approximately 0.12/100 patient-years. This is approximately 3.5-fold higher than expected in the general population.

Humira Label at 6, February 26, 2007. The label also stated that patients taking Humira for the treatment of Crohn's disease are subject to risks similar to those of patients taking Humira for the treatment of rheumatoid arthritis:

> Crohn's Disease Clinical Studies
> HUMIRA has been studied in 1478 patients with Crohn's disease in four placebo-controlled and two open-label extension studies. The safety profile for patients with Crohn's disease treated with HUMIRA was similar to the safety profile seen in patients with rheumatoid arthritis.

Id. at 12. Abbott Labs argues that the pre-February, 2007 warnings were adequate because they sufficiently warned physicians of the risk of lymphoma in the context of taking Humira to treat rheumatoid arthritis. This argument misses the mark. Warnings concerning the use of Humira to treat rheumatoid arthritis cannot necessarily be read to warn against the use of the drug to treat

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Crohn's disease.

Abbott Labs asserts that the post-February, 2007 warnings were adequate because they included specific warnings about increased rates of lymphoma in Crohn's disease patients. However, the warnings did not discuss a particular risk of lymphoma if Humira were taken in combination with immunomodulator drugs like 6-mercaptopurine, even though Abbott Labs allegedly knew before February, 2007 that Humira was routinely used in combination with immunomodulating drugs. Further, whether a warning is adequate is usually a question of fact. Jackson v. Deft, Inc. 223 Cal. App. 3d 1305, 1320 (1990) ("In most cases, however, the adequacy of a warning is a question of fact for the jury."); Miles Laboratories, Inc. v. Superior Court, 133 Cal. App. 3d 587, 596 (1982); Stanley Industries, Inc. v. W.M. Barr & Co., Inc., 784 F. Supp. 1570, 1575 (S.D. Fla. 1992); see also, Anderson v. Owens-Corning Fiberglass Corp., 53 Cal. 3d 987, 1002-1003 (1991); Gonzales v. Carmenita Ford Truck Sales, Inc., 192 Cal. App. 3d 1143, 1148-1149 (1987); Rosburg v. Minnesota Mining & Mfg. Co., 181 Cal. App. 3d 726, 734 (1986). Accordingly, the Court denies Abbott Labs' motion to dismiss based on the adequacy of the warning labels.

B. Failure To Warn

Under California law, negligence and strict liability failure-to-warn claims have similar but distinct legal standards. As explained in Anderson v. Owens-Corning Fiberglas Corp., (1991) 53 Cal. 3d 987, 1002-1003 (1991):

> Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.

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> Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.

Plaintiffs have alleged the following facts, which are sufficient to plead that Abbott Labs knew or should have known of the alleged risks of hepatosplenic T-cell lymphoma at the time Maxx was treated with Humira: (1) Remicade and Humira are very similar drugs used to treat a class of disorders which share common features; (2) a 2005 article in the Journal of Pediatric Gastroenterology reported a case of hepatosplenic T-cell lymphoma in an adolescent patient taking Remicade in combination with 6-mercaptopurine; (3) in May, 2006 the FDA required Remicade to include a new warning about the risk of hepatosplenic T-cell lymphoma in pediatric patients or young adults taking the drug concomitantly with 6-mercaptopurine for Crohn's disease; (4) in February, 2007, the FDA approved Humira for the treatment of Crohn's disease and the label on the drug was updated to state that, when used for the treatment of Crohn's disease, "immunomodulatory agents (e.g. 6-mercaptopurine and azathiorpine) may be continued during treatment with Humira;" (5) in June, 2008, the FDA issued an "Early Communication about an Ongoing Safety Review of Tumor Necrosis Factor (TNF) Blockers (marketed as Remicade, Embrel, Humira, and Cimzia)," which stated that, from 1998 to 2008, there were thirty reports of cancer in children and young adults when taking these drugs in combination with other

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immunosuppressive medicines; and (6) in July, 2008, a U.K. Abbott Labs affiliate disclosed three reports of hepatosplenic T-cell lymphoma in patients taking Humira since its release in the U.K. in December, 2002. Taken together, these facts are adequate to plead that, at the time Maxx took Humira, Abbott Labs knew or should have known of the possible association between concomitant use of TNF blockers and immunomodulators.

C. Causation

Abbott Labs argues that Plaintiffs have failed to allege facts establishing that its alleged failure to warn proximately caused Maxx's injuries. Plaintiffs plead, "Had the labels on Defendants' products properly warned about the risk of harm associated with the foreseeable uses of Defendants' products . . . Maxx Wendell and/or his parents . . . would have been allowed the opportunity to provide their informed consent to use or not to use the product." 1AC ¶ 59. This allegation, when read in the context of the entire complaint, is adequate under the liberal notice pleading standards of the Federal Rules of Civil Procedure.

D. Punitive Damages

Abbott Labs argues that Plaintiffs' prayer for punitive damages should be stricken because Plaintiffs have not alleged any facts concerning malice by any individual corporate officer. Plaintiffs concede this point. Accordingly, the Court strikes the punitive damages prayer and allegations.

CONCLUSION

For the foregoing reasons, the Court denies Abbott Labs' motion to dismiss. Docket No. 105. The Court grants the remaining Defendants' motion for judgment on the pleadings. Docket No. 115.

Plaintiffs are granted leave to amend their complaint to allege negligence and strict liability against the non-Abbott Defendants and to cure the deficiencies noted above. If Plaintiffs file an amended complaint, Defendants may file a motion to dismiss two weeks thereafter, with Plaintiffs' opposition due two weeks following and Defendants' reply due one week after that. If Plaintiffs do not file an amended complaint, their claims against the remaining Defendants will be dismissed for failure to prosecute.

IT IS SO ORDERED.

Dated: 06/14/10

Claudia Wilken

CLAUDIA WILKEN
United States District Judge

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